



MARAA PCA Infusion Pump

For Use with Narcotics at 1 mg/ml Concentration

C L I N I C I A N M A N U A L



MORE THAN PAIN RELIEF...
SUPERIOR PAIN CONTROL



TYPE BF



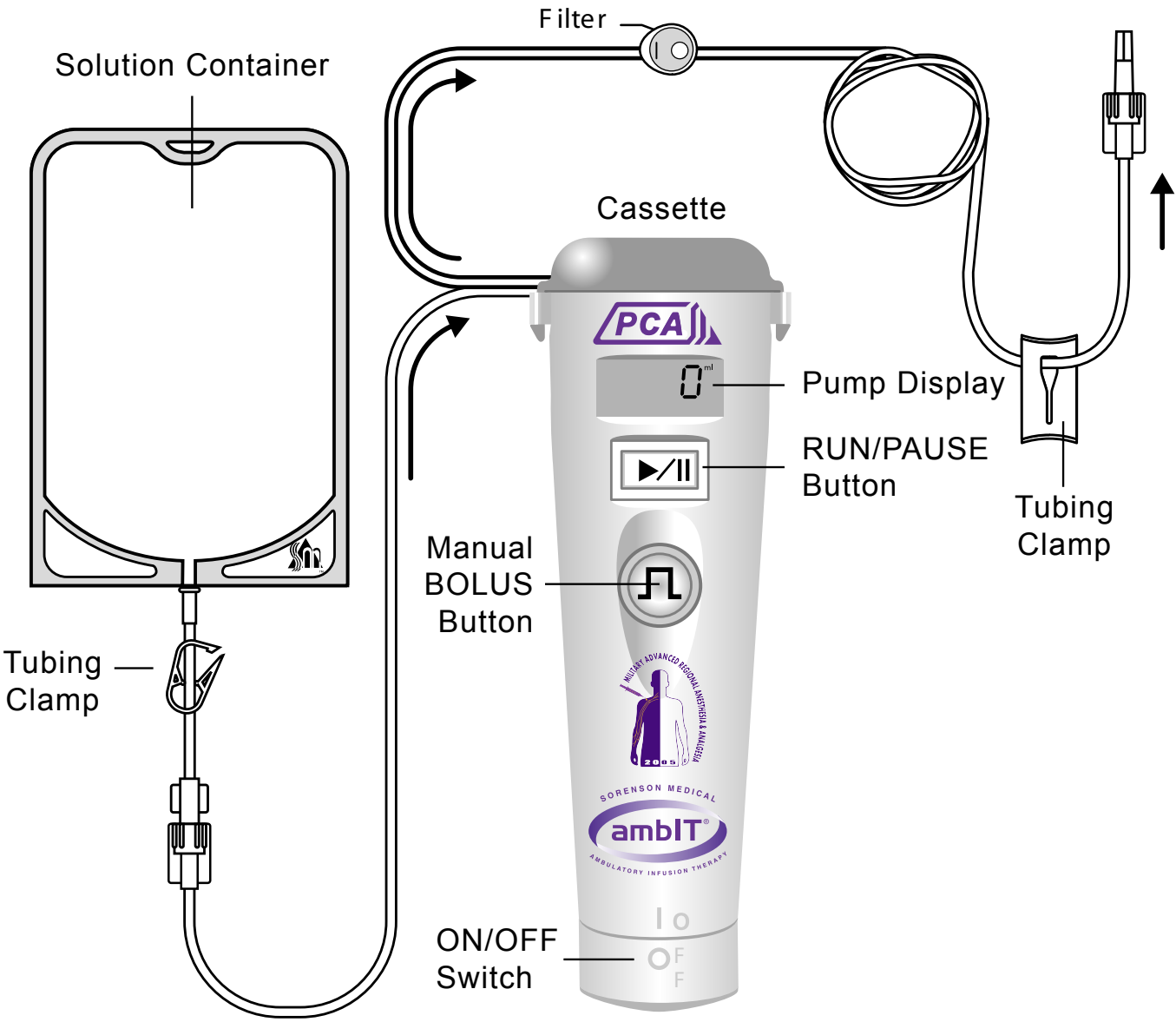
NRTL/C

IPX1



SORENSEN MEDICAL

Become Familiar with the MARAA PCA Infusion Pump



MARAA PCA Infusion Pump

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SECTION 1

INTRODUCTION

1.1 Definitions and Symbols

Warning:

A warning message contains special safety emphasis and must be observed at all times. Failure to observe a WARNING message is potentially life threatening.

Caution:

A caution usually appears in front of a procedure or statement. Failure to observe a CAUTION could result in serious patient or user injury.

Note:

A note highlights information that acts as a reminder or helps explain a concept or procedure.



This international symbol means: Attention, consult accompanying documents.

IPX1

Protected from dripping water.



TYPE BF

This is the IEC symbol for TYPE BF equipment.

- IEC Classification Internally Powered.



- The ambIT® Pump complies with EN 60601-1:1990 including amendments A1 and A2; IEC 60601-1:1998; IEC 60601-2-24:1998; CAN/CSA C22.2 No. 601-M90 with supplement No. 1-94; UL2601-1:1997 with amendments 1 and 2.

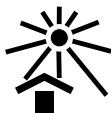


NRTL/C

The “NRTL/C” indicator adjacent to the CSA (Canadian Standards Association) Mark signifies the product has been evaluated to the applicable ANSI/UL and CSA standards, for use in the U.S. and Canada. NRTL (Nationally Recognized Testing Laboratory) is a designation granted by the U.S. Occupational Safety and Health Administration (OSHA) to laboratories which have been recognized to perform certification to U.S. Standards.



Do not re-use (Cassettes)



Keep away from heat



Keep dry



Temperature limitation



Sterilized using irradiation



DEHP-free fluid path



LATEX -free



Indicates which tubing connects to the solution container



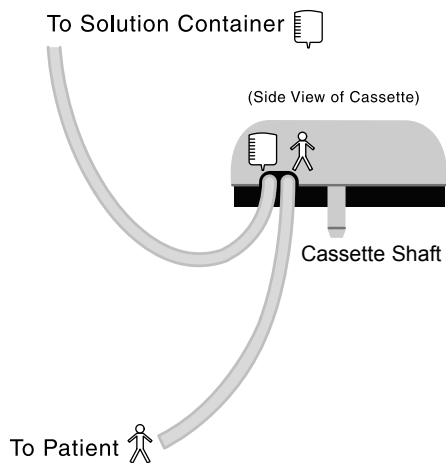
Indicates which tubing connects to the patient



Bolus



Program Lockout





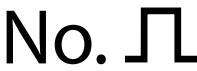
Bolus Lockout Time in hours : minutes



Bolus Volume in milliliters



Basal Infusion Rate in ml/hr



Number of Boluses Delivered



Number of Bolus Requests



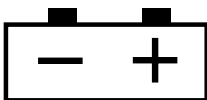
Volume to be Infused



RUN/PAUSE Button



BOLUS Button







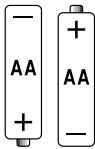
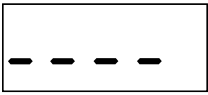



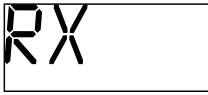
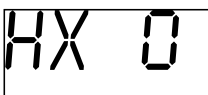
Low/Dead Battery Indicator



Alarm Indicator



MARAA PCA Infusion Pump Display

	Pump Power ON	
	Pump Power OFF	
	Battery Orientation	
	Program Lockout Code	
	Program Lock Mode	
	Pump Program Mode	
	Infusion History Report	
	Review Pump Program	
	Pump Infusion History Cleared	

1.2 Warnings

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

This product should only be used by a physician or by a trained individual under direct supervision of a physician.

For use with narcotics at 1 mg/ml concentration.

Read instructions before use. The Pump must be used strictly in accordance with these instructions.

Safe use of this Pump is the primary responsibility of the user. The user is responsible for monitoring this Pump. Contact clinical/technical support if Pump appears to be operating incorrectly.

The Pump must be used only by the person for whom it is prescribed.

The patient should never perform any function or push any button unless instructed by their health care professional.

Do not allow the Pump to get wet. If the Pump is immersed in any liquid, it must be replaced with a new Pump.

Transport and storage conditions: -7°C to 70°C (20°F to 158°F), 10% to 90% relative humidity and 500 hPa to 1060 hPa atmospheric pressure.

Operating conditions: 10°C to 43°C (50°F to 110°F), 10% to 90% relative humidity and 500 hPa to 1060 hPa atmospheric pressure.

Never attempt to open the Pump case. Only the battery cover may be removed when changing batteries. If the Pump is dropped, it must be replaced with a new Pump.

This Pump is not to be used for infusion of blood or blood products.

This pump is not to be used for infusion of life sustaining medications.

Failure to follow manufacturer's instructions while replacing batteries may result in loss of program settings and report data. Dispose of batteries properly after use.

Safety hazards such as under infusion may be associated with external radio frequency interference (RFI) or electromagnetic radiation. Typical equipment which may generate such radiation include x-ray machines, MRI equipment, and any other non-shielded electrical equipment.

The MARAA PCA Infusion Pump Cassette is a sterile, disposable administration set.

- Carefully examine each Cassette before use. Make sure there are no damaged, or missing parts.
- Do not use a Cassette if the outer package is torn, punctured, wet or damaged.
- Do not touch sterile open end of tubing. Use aseptic technique.
- Do not re-sterilize Cassette.

Protection from air infusion:

- The solution must be provided in a non-vented, collapsible container.
- Remove all air from solution container and tubing before use.

Safety hazards are associated with the interconnection of other infusion systems. Refer to: Terry, Judy (Ed.), Intravenous Therapy, W. B. Sanders Co. 1995, pp 192–193.

The Cassette should not be used for infusion volumes greater than two (2) liters.

In order to minimize the possibility of infection, Cassettes should be changed in accordance with your institution's policies.

When the desired volume to be infused has been delivered, the empty solution container must be changed. Failure to do so may result in cessation of fluid delivery.

Before starting therapy, check that all connections are secure and there are no leaks in the fluid path.

Bolus and infusion history reports should never take the place of good clinical judgement. Always perform a clinical evaluation whenever interpreting these reports.

Infusing viscous solutions (e.g. D25W) into high pressures (e.g. approaching 300mm Hg) may decrease volumetric accuracy.

Section 1.3 Indications for Use

The MARAA PCA Infusion Pump is intended for use by surgeons and anesthesiologists for the perioperative and post operative infusion of narcotics for pain management at 1 mg/ml concentration.

1.4 Overview

The MARAA PCA Infusion Pump is intended for the ambulatory infusion of fluids. The Pump has simple controls that are easily operated by both caregivers and patients.

The clinician may select different delivery profiles which include, basal rate only, basal rate with PCA (Patient Controlled Analgesia) bolus or PCA bolus only.

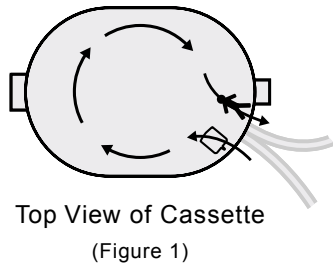
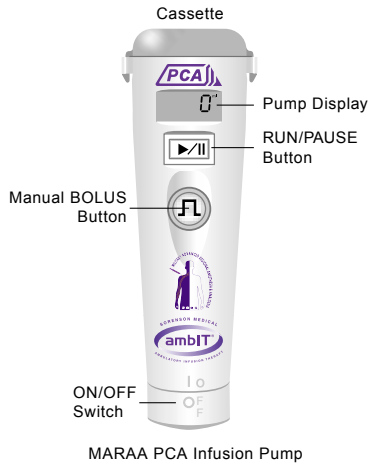
1.5 Product Description

MARAA PCA Infusion Pump

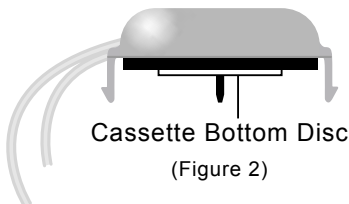
The Pump program is determined by selecting one of the four (4) Preset and one (1) User-Defined programs during the Programming mode. A specific combination of pushing the Pump's buttons allows the user to access the Programming mode. This special combination of pressing buttons is designed to prevent inadvertent or unauthorized adjustments.

The **RUN/PAUSE** button is located just below the Pump display. This button is used to start, pause or resume the infusion and silence alarms. The **RUN/PAUSE** button toggle between Run and Pause. A blinking green Run light (inside the **BOLUS** button) and "ml" (volume infused) in the Pump display indicate the Pump is infusing.

If the infusion is paused, a blinking Pause symbol (II) in the Pump display and two (2) beeps every four (4) minutes indicate that the Pump infusion has been temporarily stopped. The **BOLUS** button is placed below the **RUN/PAUSE** button. When pressed in Run mode, the pump will deliver the programmed bolus dose. During bolus delivery, the green Run light (inside the **BOLUS** button) will double blink. The table in Section 7 of this manual describes each alarm and signal.



Top View of Cassette
(Figure 1)

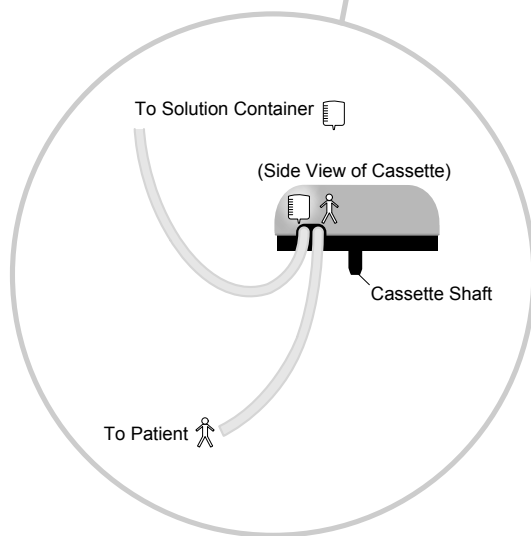
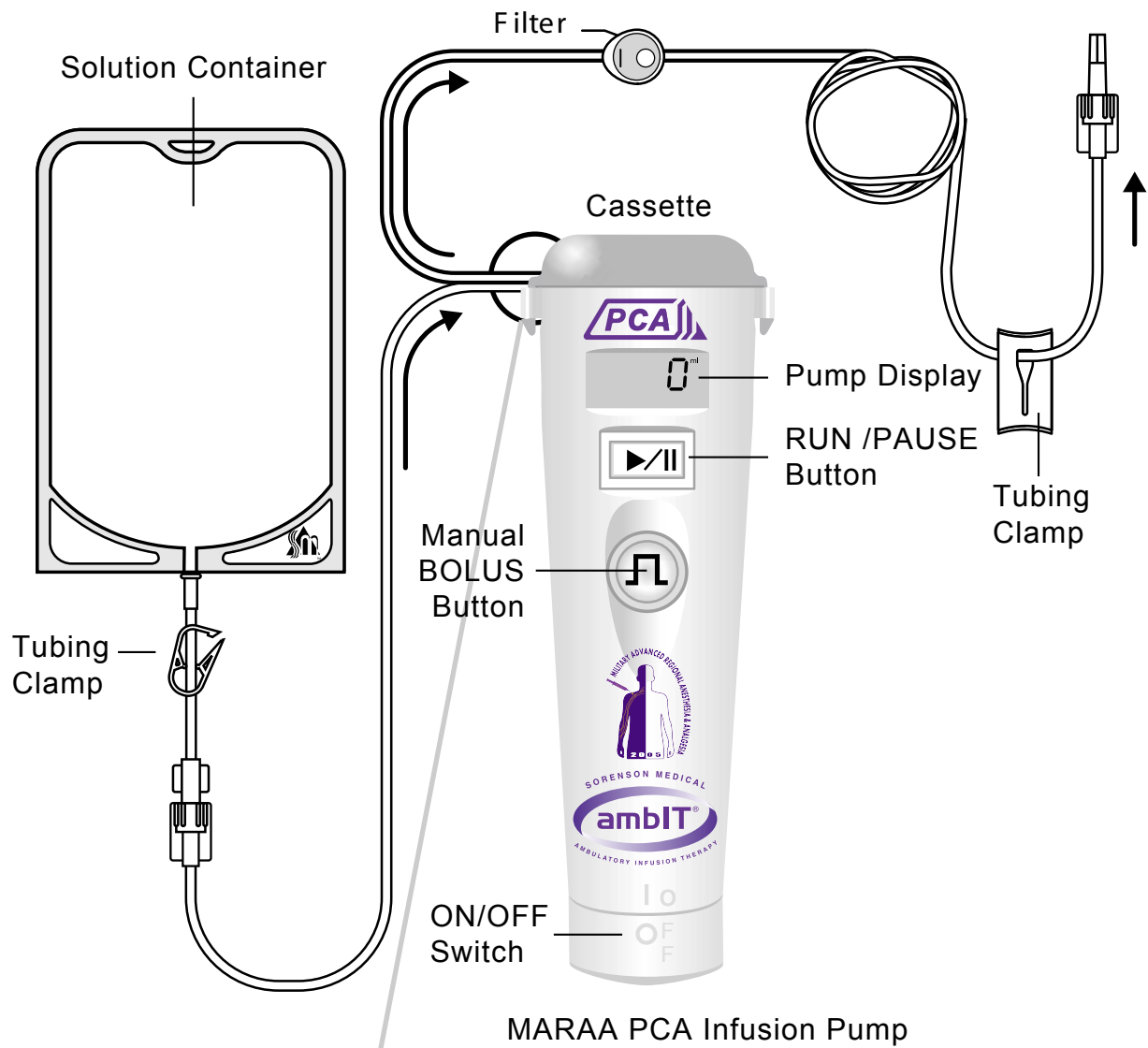


Cassette Bottom Disc
(Figure 2)

MARAA PCA Infusion Pump Cassette

The Cassette contains a rotary mechanism that pumps the infusion solution at an accurate and controlled rate.

During Cassette priming, fluid will flow freely through the tubing (Figure 1). After priming, snapping the Cassette bottom disc into the body of the Cassette closes the fluid path preventing the free flow of fluid (Figure 2). When primed, the Cassette simply snaps onto the Pump.



(See Diagram
on Page 8)

SECTION 2 SET UP

Warning: Protection from air infusion

- The infusion solution must be provided in a non-vented, collapsible container.
- Remove all air from solution container and tubing before use.

2.1 Required Materials

Infusion with the Pump requires the use of the following ambIT® Pump Cassette:

- ambIT® Cassette, Filter, Male Luer (1.2 micron air eliminating filter) Ref 220266

The Cassette is a sterile, disposable administration set. The upstream (short) tubing of the Cassette connects to a non-vented, collapsible solution container. Once the Cassette has been primed, the down stream extension (long) tubing of the Cassette connects to the patient's access device.

Note:

Using the Male Luer Lock/Spike adaptor gives the capability of using any spike medication bag up to 1000ml.

2.2 Priming Cassette

Warnings:

Do not use a Cassette if the outer package is torn, punctured, wet or damaged.

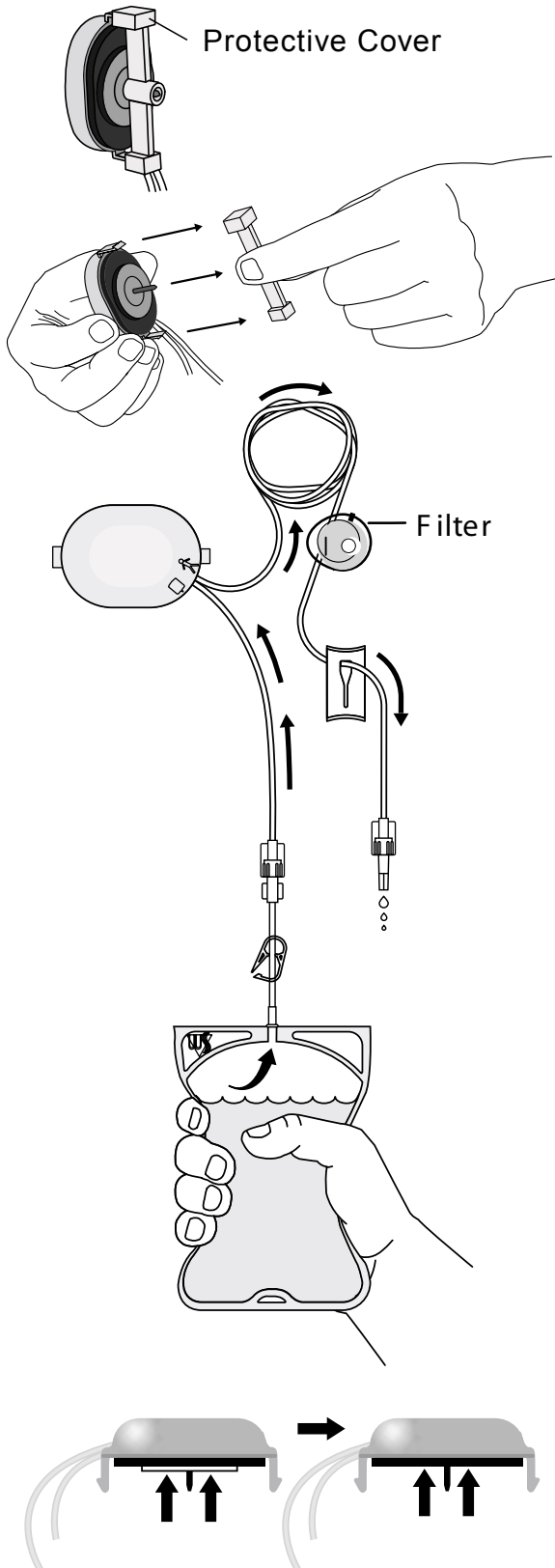
Do not touch sterile open ends of the tubing. Use aseptic technique.

Remove all air from solution container and tubing before use.

Be sure all connections are secure before starting therapy and check fluid path for leaks.

If filled solution container is not going to be used immediately, clamp the tubing and cap the female luer connector with the protective cap provided, to prevent contamination.

Always verify the Cassette bottom disc is snapped closed before attaching Cassette to Pump.



To prime the Cassette, follow these steps:

STEP 1

Remove protective cover from bottom of Cassette as shown.

STEP 2

Connect the solution container to the Cassette using aseptic technique.

STEP 3

Release all clamps on tubing.

STEP 4

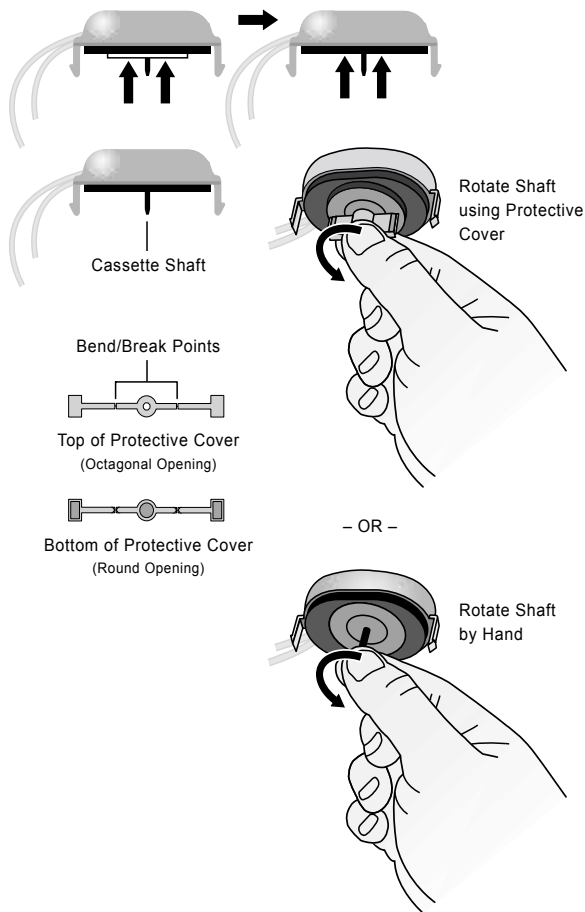
Invert the solution container to allow air to be evacuated first before priming the Cassette with fluid (see illustration).

STEP 5

Gently squeeze the solution to force fluid and air upward through the tubing and Cassette. Continue until the solution has completely filled the tubing and all air bubbles have been removed.

STEP 6

After priming, close the fluid path by snapping the Cassette bottom disc into the Cassette body. This will prevent free flow.

**Note:**

In the event the Cassette bottom disc is snapped closed before the priming process is complete, place the Cassette on the Pump (not attached to patient) and use the BOLUS button to complete the priming of the Cassette.

Important Information

To help ensure a successful infusion, please include the following steps:

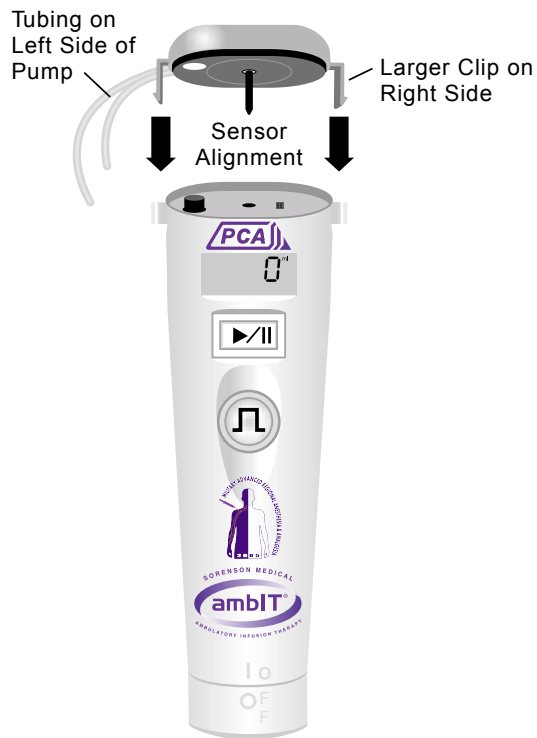
1. Before placing the Cassette on the Pump:

- Prime the tubing (set aside the protective cover).
- Press the Cassette bottom disc into the Cassette Body as shown.
- Bend or break away the wings of the protective cover. Place the protective cover back on Cassette (insert Cassette Shaft into octagonal opening). Use protective cover to rotate Cassette Shaft counterclockwise three (3) or four (4) times.

Note:

The Cassette Shaft can also be rotated by hand.

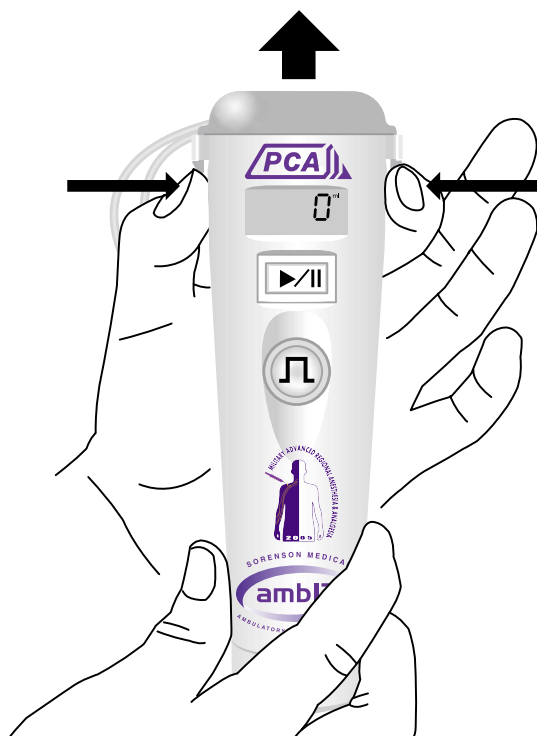
- Most "MA" alarms can be resolved by pressing the **RUN/PAUSE** button to silence the alarm. To restart the infusion, the **RUN/PAUSE** button will need to be pressed for five (5) seconds. If the alarm persists, contact Sorenson Medical, Inc.
- Make sure the patient is instructed on the proper use of the Pump.



MARAA PCA Infusion Pump

2.3 Attach Cassette To Pump

Insert the Cassette onto the top of the Pump, as shown. Gently squeeze tabs on Cassette to attach onto Pump.



2.4 Remove Cassette From Pump

To remove the Cassette, press both Cassette release tabs at the same time and lift the Cassette off the Pump

Caution:

Do not remove Cassette while the green Run light is blinking. First place Pump in **PAUSE**.

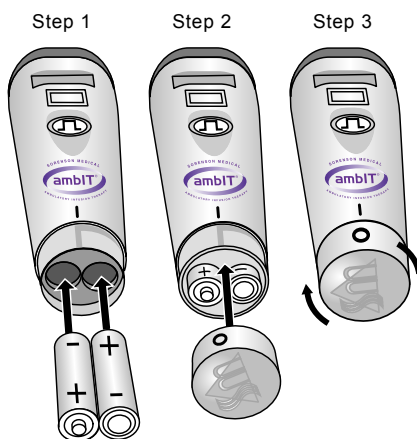
2.5 Battery Installation and Replacement

The Pump is powered by two (2) AA alkaline 1.5V batteries.

Caution:

Sorenson Medical has not tested all rechargeable batteries with the pump; therefore we cannot ensure that a specific rechargeable battery will power the pump for a period of time. The battery condition and pump settings will determine how the battery will perform in the pump. For this reason the time before the low battery alarm occurs and the time between low and dead battery alarms is difficult to predict with non-alkaline batteries. We recommend you change the batteries at the end of each therapy.

The Pump memory is designed to retain program settings and infusion history for up to six (6) months without power. Failure to follow manufacturer's instructions while replacing batteries may result in loss of program settings and report data. Do not store batteries in the Pump.



2.5.1 Battery Installation

To install batteries see illustration.

STEP 1: Insert batteries according to illustration

STEP 2: Place battery cover on Pump as illustrated in diagram (**OFF** symbol (O) on cover) slightly to left of the (I) mark on the Pump).

STEP 3: Rotate battery cover clockwise to the **OFF** (O) position

2.5.2 Battery Replacement

To replace batteries:

STEP 1: Place Pump in **PAUSE**

STEP 2: Rotate battery cover counterclockwise slightly to the left of the **OFF** (O) position until the cover stops or meets resistance.

STEP 3: Remove cover and replace batteries according to instructions in section 2.5.1.

After battery replacement the Pump will return to the Pause mode.

Press the **RUN/PAUSE** button to review the current program settings.

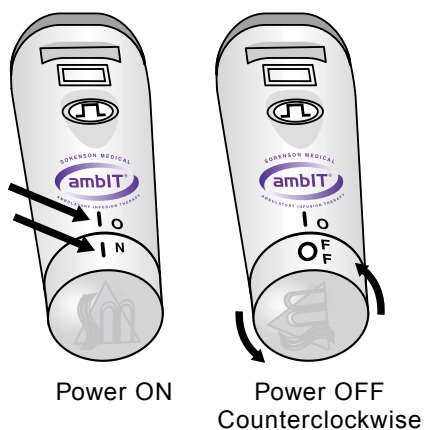
Press the **RUN/PAUSE** button for five (5) seconds to resume the current infusion program.

Warning:

When reinstalling batteries, always verify correct program settings.

Caution:

Verify the Pump is in **PAUSE** before removing batteries.



2.6 ambIT® Power ON and OFF

To power on the Pump, rotate the battery cover clockwise until the (I) mark lines up with the (I) mark on the Pump.

To power off the Pump:

STEP 1: Place the Pump in **PAUSE**.

STEP 2: Rotate the battery cover counterclockwise until the (O) mark lines up with the (I) mark on the Pump. (See illustration)

Note:

After the power on self-test, the Pump will beep twice and go into the Pause mode. The clinician can now program the Pump or resume current infusion settings.

SECTION 3

PROGRAMMING INSTRUCTIONS

3.1 General Information

The Pump must be programmed and have the history cleared before administering solution. The Pump has two (2) buttons, the **RUN/PAUSE** and the **BOLUS** buttons. A specific combination of pushing these buttons sets the Pump program.

Follow these steps to enter the Programming mode:

STEP 1: Place the Pump in **PAUSE**.

STEP 2: Press and hold down both the **RUN/PAUSE** button and the **BOLUS** button for two (2) seconds until one (1) beep sounds

STEP 3: “**PRO**” will appear in the pump display.

Next, the “**PRO**” will appear and the Program #, 1 - 5, will blink in the Pump display indicating this number can be changed. Remaining steps for programming the Pump are shown in Sections 3.2 - 3.6.

The Pump can be reprogrammed during infusion, without clearing the infusion history, by placing the Pump in **PAUSE** and entering the Programming mode. See Section 3.4 Programming Steps.

The Pump can be reprogrammed after clearing the infusion history (see Section 5.2 Clearing Pump Infusion History) by entering the Programming mode and selecting the desired parameters.

Note:

- When attempting to program/reprogram the Pump, **LOC** will appear in the Pump display if the Pump program is in the Lock mode (see Section 6 - Patient Lockout).
- The Pump program must be unlocked for programming/reprogramming and clearing infusion History.

3.2 Pump Delivery Profiles

Please refer to Section 3.1 General Information. The Pump can be programmed to provide five (5) Preset Programs (see table below), bolus, basal rate only, or PCA bolus only. Basal flow rates range from 0 ml/hr to 20 ml/hr and can be adjusted in 0.1 ml/hr increments. Bolus volumes range from 0 to 20 ml, in 0.1 ml increments. Refer to the table below for all possible program settings.

PRO <input type="checkbox"/> <input type="checkbox"/>	Basal <input type="checkbox"/> <input type="checkbox"/>	Bolus <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Bolus Lockout <input type="checkbox"/>	Volume
1 <input type="checkbox"/> <input type="checkbox"/>	0 <input type="checkbox"/> <input type="checkbox"/>	1 <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	6 min <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	25-1000ml
2 <input type="checkbox"/> <input type="checkbox"/>	0 <input type="checkbox"/> <input type="checkbox"/>	1 <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	10 min <input type="checkbox"/>	25-1000ml
3 <input type="checkbox"/> <input type="checkbox"/>	0 <input type="checkbox"/> <input type="checkbox"/>	2 <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	6 min <input type="checkbox"/> <input type="checkbox"/>	25-1000ml
4 <input type="checkbox"/> <input type="checkbox"/>	0 <input type="checkbox"/> <input type="checkbox"/>	2 <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	10 min <input type="checkbox"/>	25-1000ml
5 <input type="checkbox"/> <input type="checkbox"/>	Set own <input type="checkbox"/>	Set own <input type="checkbox"/> <input type="checkbox"/>	Set own	25-1000ml

3.2.1 Option with Program #5

Available Program Settings for Program #5	
Basal Flow Rate (ml/hr)	0 - 20 in 0.1 ml/hr increments
Bolus Dose Volume (ml)	0 - 20 in 0.1 ml increments
Bolus Lockout Time (HH:MM)	00:06, 00:10, 00:15, 00:20, 00:30, 00:45, 1:00, 1:30, 2:00, 4:00 8:00, 12:00
Volume to be Infused (ml)	25, 50, 75, 100, 150, 175, 200, 250, 300, 350, 400, 450, 500, 600, 700, 800, 900, 1000

3.2.2 Basal Rate with PCA BOLUS

To infuse a basal rate with a PCA bolus, set the infusion rate, bolus volume, bolus lockout time, and volume to be infused to the desired parameters.

3.2.3 Basal Rate Only

To infuse a basal rate only, select the basal infusion rate (ml/hr). Set the bolus dose volume at "0" followed by the volume to be infused.

Note:

If bolus volume is set at "0", lockout time will not display.

3.2.4 PCA Bolus Only

To infuse a PCA bolus only, set the basal infusion rate to "0". Set the bolus volume and bolus lockout time followed by the volume to be infused.

3.3 Program Parameters

The parameters that may be programmed into the Pump are as follows:










- Preset Programs: The four (4) Preset and one (1) User-Defined Infusion Profiles.
- Basal Infusion Rate: The constant infusion flow rate provided by the Pump. Rate is expressed in milliliters per hour (ml/hr).
- Bolus Volume: The amount of drug infused upon request by pressing the **BOLUS** button. Bolus volume is expressed in milliliters (ml).
- Bolus Lockout Time: The time period after the last bolus delivery in which another bolus is not allowed. Bolus lockout time is expressed in hours and minutes (**HH:MM**). The **BOLUS** button will not deliver a bolus during this time.
- Volume to be Infused: The total amount of fluid in the solution container to be infused. When this amount has been infused, the “Infusion Complete” alert (one (1) long tone followed by three (3) short beeps every four (4) minutes) will sound and the “Bag” icon in the Pump display will appear.

Warning:

When the desired volume to be infused has been delivered, and the “Infusion Complete” alert has sounded, the Pump will deliver a KVO rate (0.5 ml/hr) until the Pump is reset (history cleared) or turned off. If the basal infusion rate is less than 0.5 ml/hr the Pump will continue at the set basal rate.

The Pump should be programmed by a physician or under the direction of a physician. Patients should be instructed not to program the Pump or attempt to change the program.

3.4 Programming Steps

ACTION	SOUND	PUMP DISPLAY
To enter the Programming mode: From Pause mode, press and hold down both the RUN/PAUSE button and the BOLUS button for 2 seconds.	1 Beep	"PRO" displays for 2 seconds to indicate the pump is in programming mode. Basal flow rate is displayed in ml/hr. 
Set Program # 1 - 5. If Program # 1 - 4 is selected, go to "Setting the Volume to be Infused"; otherwise, select Program # 5.	1 Beep	"PRO 1" displays 
Setting Basal Flow Rate: Press the RUN/PAUSE button to increase the rate or press the BOLUS button to decrease the rate (0 - 20). When the desired rate appears in the display, press and hold either the RUN/PAUSE button or the BOLUS button for 2 seconds to accept the rate.	1 Beep	Number left of decimal point flashes alternately with "ml/hr" 
Repeat the same steps to set rate right of the decimal point (.0 - .9).	1 Beep	Number right of decimal point flashes alternately with "ml/hr"  Basal flow rate is established.
Setting Bolus Dose Volume: Press the RUN/PAUSE button to increase the volume or press the BOLUS button to decrease the volume (0 - 20). When the desired volume appears in the display, press and hold either the RUN/PAUSE button or the BOLUS button for 2 seconds to accept the volume.	1 Beep	Bolus dose volume is displayed in ml. Number left of decimal point flashes alternately with ml and bolus icon. 
Repeat the same steps to set rate right of the decimal point (.0 - .9).	1 Beep	Number right of decimal point flashes alternately with ml and bolus icon.  Bolus dose volume is established.
Setting the Bolus Lockout Time: Press the RUN/PAUSE button to increase the time or press the BOLUS button to decrease the time. When the desired lockout time appears in the display, press and hold either the RUN/PAUSE button or the BOLUS button for 2 seconds to accept the lockout time.	1 Beep	Bolus lockout time is displayed in hours and minutes. hr:min is displayed with bolus, lock, and clock icon flashing.  Note: If BOLUS Dose Volume is set to "0", this step will be skipped. Bolus Lockout is established.
Setting the Volume to be Infused: Press the RUN/PAUSE button to increase the volume or press the BOLUS button to decrease the volume. When the desired volume appears in the display, press and hold either the RUN/PAUSE button or the BOLUS button for 2 seconds to accept the volume to be infused.	2 Beeps	Volume to be infused is displayed in ml with bag icon flashing.  Volume to be infused is established.
		Pump returns to Pause with Pause indicator flashing.  Note: To confirm program settings (3.4), access Rx by pressing the BOLUS button one time. Pump will scroll through programmed settings and return to Pause.

To accept the current program settings in each step and not make any changes, press and hold the **RUN/PAUSE** and/or **BOLUS** buttons for 2 seconds until 1 beep sounds.

Note: Numbers are for example only.

3.5 Program Review

Caution:












After programming Pump, always verify the program by performing a program review.

To review the Pump program:

STEP 1: Place Pump in **PAUSE**.

STEP 2: Press the **BOLUS** button one (1) time.

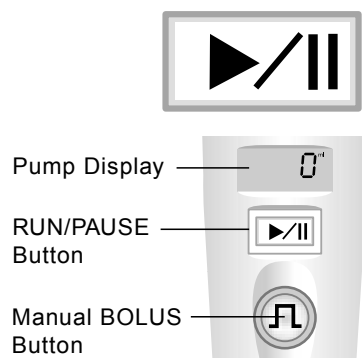
"**RX**" will appear in the display and the Pump will scroll through program number choice, RX, PRO #, Basal Rate, Bolus Volume, Lockout Time (if BOLUS > 0), and Bag Volume in the sequence shown on the table below. After the review, the Pump will return to **PAUSE** and be ready to begin or resume the infusion.

Symbols	Parameter
"PRO"      	Program "PRO"
ml/hr	Basal Flow Rate
Bolus icon  and ml	Bolus Dose Volume
Bolus  , Lock  and Clock  icons	Bolus Lockout Time
Bag Volume  icon and ml	Total Volume to be Infused

3.6 Summary of Programming Controls

Activity	Steps	Audible	Visual
Program/ Reprogramming Pump	From Pause mode, press and hold down both the BOLUS button and the RUN/PAUSE button for 2 seconds	1 beep	" PRO " - Parameters can now be changed.
Review and verify program settings	While Pump is in Pause, press the BOLUS button	1 beep	" RX " - Display cycles through each programmed parameter.
Review Infusion History	While Pump is in Pause, press and hold down the BOLUS button for 2 seconds	1 beep	" HX " - Display cycles through each Infusion History parameter.
Clear Infusion History and begin new infusion	Upon entering the Infusion History (above), release and immediately hold down the BOLUS button again for 2 more seconds Note: Pressing the RUN/PAUSE button will repeat the same Pump program	1 beep	" HX 0 " - Display shows "HX 0" to verify history has been cleared.

SECTION 4 OPERATING INSTRUCTIONS



4.1 Start Infusion

Note:

Before starting infusion, the Pump must be programmed. See Section 3 Programming Instructions for details.

To begin an infusion, with the Pump in Pause, press the **RUN/PAUSE** button. The **RUN/PAUSE** button is located directly below the Pump display.

The green Run light (inside the **BOLUS** button) will start to blink and the "ml" (volume infused) will appear in the Pump display.



4.2 Pause Infusion

To **PAUSE** the infusion, press and hold the **RUN/PAUSE** button until one (1) beep is heard (five [5] seconds). The Pump will beep two (2) times, the green Run light will stop blinking, and the Pause (**II**) icon will blink in the Pump display. If left in Pause, the Pump will beep two (2) times every four (4) minutes.

Note:

PAUSE temporarily stops the infusion. While in **PAUSE**, the infusion is delayed. This allows for changing the Cassette, solution container, or batteries.



4.3 Resume Infusion

To resume the infusion from **PAUSE**, push and hold the **RUN/PAUSE** button for five (5) seconds.

The display will show the "ml" (volume infused) and the green Run light will start to blink. The infusion will resume at the same point as when the Pump was placed in **PAUSE**.



4.4 Silence Alarm

To silence an alarm, push the **RUN/PAUSE** button. When the alarm has been silenced, the Pump will remain in **PAUSE**. Once the cause of the alarm has been corrected, press the **RUN/PAUSE** button to resume the infusion.

Note:

If the Pump alarms due to downstream pressure and the cause of the alarm is corrected without intervention, the alarm will silence and the Pump will resume the infusion automatically.



4.5 Bolus Activation

The **BOLUS** button is located on the Pump directly below the **RUN/PAUSE** button. Every time the **BOLUS** button is pressed during the infusion, the Pump will beep once. If the **BOLUS** dose is permitted, the Pump will begin bolus administration. During **BOLUS** infusion, the green Run light will double blink. If the **BOLUS** button is pressed during the Bolus lockout time, the Pump will beep once, but no Bolus will be delivered.

Note:

- **BOLUS** button is disabled when bolus volume is set to 0 ml.
- Flow rate during bolus is 100 ml/hr.
- The **BOLUS** button is disabled if the volume to be infused has been delivered. During this time, if the **BOLUS** button is pressed, the "Infusion complete" alert will sound.

4.6 Summary of Operating Controls

To:	Steps to Take	Audible Indicator	Visual Indicator
Start Infusion	Program Pump, then Press RUN/PAUSE button. RUN/PAUSE button must be pressed for 5 seconds	None	Green Run light blinks (inside BOLUS button) and "ml" (volume infused) is in Pump display
Pause Infusion	Press and hold RUN/PAUSE button for 5 seconds	2 beeps	Pause (II) icon flashing in display
Silence Alarm	Press RUN/PAUSE button one time	Alarm sound stops	Pause (II) icon flashing in display
Bolus Delivery	Press BOLUS button one time.	1 Beep	Green Run light double blinks

SECTION 5

INFUSION HISTORY REPORTS

5.1 Pump Infusion History

To obtain the Pump Infusion History:

STEP 1: Place Pump in **PAUSE**.

STEP 2: Press and hold down the **BOLUS** button for two (2) seconds, until one (1) beep sounds and "**HX**" is displayed.

Note:

The remote **BOLUS** button may be used to review Infusion History.

The Pump will cycle through the following parameters:

Infusion History	Visual Indicator
Total volume infused including boluses in ml	ml
Total number of boluses actually delivered	No. and \sqcup
Total number of bolus requests	No. and $\textcircled{\sqcup}$
Elapsed Time (Time pump has been in run mode since history was cleared.)	" $\textcircled{\downarrow}$ " and hr:min **After 100 hours, Pump will only display hours (not minutes)

The displayed parameters indicate history since the last time the Pump history was cleared as explained in Section 5.2.

5.2 Clearing Pump Infusion History

To clear the Pump Infusion History:

STEP 1: Place Pump in **PAUSE**

STEP 2: Press and hold down the **BOLUS** button for two (2) seconds (obtaining the Infusion History mode).

STEP 3: Upon entering the Infusion History mode (**HX**), release the **BOLUS** button and immediately press and hold the **BOLUS** button again until "**HX 0**" appears in the Pump display. This indicates the clearing of the Pump Infusion History.

Note:

- The Pump program must be unlocked for programming/reprogramming and clearing Infusion History.
- When attempting to clear the Pump Infusion History, "**LOC**" will appear in the Pump display if the Pump program is in the Lock mode (see Section 6—Patient Lockout).

SECTION 6

PATIENT LOCKOUT

The Pump has been designed with patient lockout features:

LEVEL 1 - SOFTWARE – The steps required for entering the Pump program mode should not be revealed to the patient. This prevents the unauthorized tampering with the infusion parameters.

LEVEL 2 – ACCESS CODE – The Pump includes a patient lockout feature. The Lockout mode is accessed by following these steps:

STEP 1: Place Pump in **PAUSE**.

STEP 2: Enter the Pump's Program mode by pressing and holding down both the **RUN/PAUSE** and **BOLUS** buttons at the same time until one (1) beep sounds and "**PRO**" appears in the Pump display.

STEP 3: Release both buttons and again press and hold down both buttons (**RUN/PAUSE** and **BOLUS**) for two (2) seconds, until one (1) beep sounds and four (4) dash symbols appear in the display (_ _ _ _).

To Lock the Pump:

A lock code is entered into the Pump by entering a number in each digit space of the display, starting from the right.


STEP 1: Flashing 1st digit space.

STEP 2: Press the **RUN/PAUSE** button to increase the number, press the **BOLUS** button to decrease the number.

STEP 3: When the desired number appears in the display, press and hold either the **RUN/PAUSE** button or the **BOLUS** button for two (2) seconds until one (1) beep sounds.

STEP 4: Repeat steps 1-3 to program digits two through four (2-4).

Note:

- The clinician may program 1-4 digits into the Pump for the lock code.
- If programming only 1-3 digits into the Pump for the lock code, when the desired code is programmed (eg: 12 or 123), press and hold both the **RUN/PAUSE** button and the **BOLUS** button for two (2) seconds until one(1) beep sounds. This will accept the shortened code and lock the Pump program.
- After selecting the lock mode, the Pump will return to the Pause mode and the Lock icon  will appear in the display. Current program settings can be resumed by pressing the **RUN/PAUSE** button.

To Unlock the Pump:

To unlock the Pump program, the clinician accesses the Lockout mode of the Pump, as described above. The pre-programmed code is re-entered into the Pump by entering a number in each digit space of the display, starting from the right.

STEP 1: Flashing 1st digit space.

STEP 2: Press the **RUN/PAUSE** button to increase the number, press the **BOLUS** button to decrease the number.

STEP 3: When the desired number appears in the display, press and hold either the **RUN/PAUSE** button or the **BOLUS** button for two (2) seconds until one (1) beep sounds.











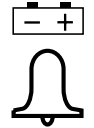


STEP 4: Repeat steps 1-3 to program digits 2-4.

Note:

- If entering only 1-3 digits for the lock code, when the code is programmed (eg: 12 or 123), press and hold both the **RUN/PAUSE** button and the **BOLUS** button for two (2) seconds until one (1) beep sounds. This will accept the shortened code and unlock the Pump program.
- After selecting the unlock mode, the Pump will return to the Program mode. The clinician can now either reprogram the Pump or verify and resume current program settings.
- In the event a code is forgotten, a default code of (5 _ _ 5) may be used to unlock the Pump program.
- The Pump program must be unlocked for programming/reprogramming and clearing Infusion History.

SECTION 7: ALARMS AND SIGNALS

7.1 Visible and Audible Alarm and Signal Table

Status	Icon	Visual Indicator	Audible Indicator	Comments
Pump Infusing Normally		Green Run light (inside BOLUS button) blinking, "ml" (volume infused) in display.	None	Periodic movement of Cassette gears is normal.
Infusion Paused		"Pause" icon blinking in display. Green Run light off.	2 beeps every 4 minutes	
Infusion Complete		"Bag" icon blinking	1 long tone followed by 3 short beeps. Repeats every 4 minutes.	"Infusion Complete" alert will sound every 4 minutes.
Bolus Infusion		Green Run light (inside BOLUS button) double blinks "Bolus" icon is displayed.	1 Beep	1 beep will sound every time the BOLUS button is pressed during Run mode.
				
Occlusion Alarm		"Alarm" icon illuminated with "OCL" in display	Constant Beeping	Press and hold the RUN/PAUSE button to silence alarm. Press and hold the RUN/PAUSE button to restart Pump. If unable to resolve (silence) alarm, contact health care professional.
Malfunction		"Alarm" icon illuminated with "MA" in display	Constant Tone	Immediately close tubing clamp. See Section 8- Troubleshooting.
Cassette not Attached to Pump		"Alarm" icon illuminated with "MA" in display	Constant Tone	Press RUN/PAUSE button to silence alarm. Gently press on top of Cassette to ensure proper placement. Resume infusion.
Malfunction		"Alarm" icon illuminated with "MA1" in display	Constant Tone	Press RUN/PAUSE button to silence alarm. Gently press on top of Cassette (assure Cassette bottom is properly sealed). Resume infusion.
Low Battery		"Battery" icon blinking	5 short beeps every 4 minutes	Replace batteries as soon as possible.
Dead Battery		"Battery" icon, "Alarm" icon illuminated	Constant Tone	Press RUN/PAUSE button to silence alarm. Alarm and battery icons will remain on. Replace batteries immediately.
Malfunction		"Alarm" icon and □ "EE1", "EE2", "EE3", "EE4", "EE5", "EE6", or "EE7" in display.	10 short beeps	Immediately close tubing clamp and turn off the pump. Contact Sorenson Medical, Inc. by calling the toll free number on the Pump.
Malfunction		"Alarm" icon and □ "CPU", "RA" or "RO" in display.	Constant Tone	Immediately close tubing clamp and turn off the pump. Contact Sorenson Medical, Inc. by calling the toll free number on the Pump.
BOLUS Button		"REL" is displayed.	Constant Beeps	Release the BOLUS button.

SECTION 8

TROUBLESHOOTING

8. Troubleshooting

Problem	Resolution	Reference
Cassette will not prime	<ul style="list-style-type: none"> • Verify that tubing clamps are open • If spike set is used, verify that spike is completely inserted into solution container • Verify that Cassette bottom disc has not been snapped into the Cassette body 	Section 2
Cassette will not attach to Pump	<ul style="list-style-type: none"> • Verify proper Cassette placement onto Pump • Verify Cassette bottom disc has been snapped into Cassette body 	Section 2
No display	<ul style="list-style-type: none"> • Insert fresh batteries • Verify proper battery placement • Verify Pump power is in the "ON" position 	Section 2
Constant beeping during infusion	Fluid path occlusion <ul style="list-style-type: none"> • Verify that tubing clamps are open • Check access device patency • Check for kink in tubing 	Section 4
Continuous tone	Malfunction <ul style="list-style-type: none"> • Possible dead battery alarm, replace batteries (battery icon visible). • Press on Cassette top to ensure proper placement. • Check Cassette <ul style="list-style-type: none"> - Remove Cassette from Pump. - Rotate Cassette spindle 1 time. - Replace Cassette on Pump. • Press RUN/PAUSE button to resume infusion. • If "MA" continues: <ul style="list-style-type: none"> - Immediately close tubing clamp. - Manufacturer's service/assistance may be required. 	
Blood backed into tubing	<ul style="list-style-type: none"> • Verify the Tube is connected correctly: Patient side connected to Patient - Bag side connected to Bag. • Verify Pump is in Run Mode • Attempt to clear tubing by delivering a Bolus • If unable to clear tubing by delivering a Bolus, close tubing clamp and replace Cassette. • If situation continues, manufacturer's service/assistance may be required. 	

SECTION 9

SPECIFICATIONS

MARAA PCA Infusion Pump - Basal Rate and/or Bolus with Infusion History Report

Volumetric Accuracy	± 6%
Maximum Basal Flow Rate	20 ml/hr
Minimum Basal Flow Rate	.1 ml/hr
Bolus Delivery Rate	100 ml/hr
Stroke Volume	50 microliters
Basal Flow Rates	0 to 20 ml/hr in .1 ml/hr steps
Bolus Dose Volumes	0 to 20 ml in .1 ml steps
Bolus Lockout Times	00:06, 00:10, 00:15, 00:20, 00:30, 00:45, 1:00, 1:30, 2:00, 4:00, 8:00, 12:00
Volume to be Infused (ml)	25, 50, 75, 100, 150, 175, 200, 250, 300, 350, 400, 450, 500 600, 700, 800, 900, 1000
Pump Mechanism	Microprocessor controlled rotary peristaltic
Maximum Infusion/Occlusion Pressures	25 +/- 12 psi
Maximum Activation Time of Occlusion Alarm (minimum rate) at Minimum Occlusion Pressures	4 Hours
Maximum Activation Time of Occlusion Alarm (intermediate rate) at Maximum Occlusion Pressures	90 Seconds
Dimensions	2.16 in. x 1.4 in. x 6.875 in (55 mm x 36 mm x 175 mm)
Weight	4.7 ounces (133.2 grams) without batteries 6.4 ounces (181.4 grams) with batteries
Power Supply, Internal	2 each AA alkaline 1.5V batteries (2 days @ 10 ml/hr)
Power Supply, External	None
Operating Controls Button	RUN/PAUSE button, BOLUS button, ON/OFF switch
Display, Audible Alarms, Signals and Reports	<ul style="list-style-type: none"> • Run Indicator Light • Bolus Infusing • Pause Indicator • Obstruction-Downstream (25 +/- 12 psi) • Cassette Not Mounted on Pump • Low Battery • Dead Battery • Malfunction • Bolus Request • Infusion Complete
History Reports	<ul style="list-style-type: none"> • Volume Infused • Bolus History—Number of Boluses Delivered • Bolus History—Number of Bolus Requests • Elapsed Time
Delivery Profiles	<ul style="list-style-type: none"> • Basal Rate + PCA Bolus • Basal Rate Only • PCA Bolus Only

Federal (U.S.A.) law restricts this device to sale by or on order of a physician.

SECTION 10

DELIVERY RATE ACCURACY

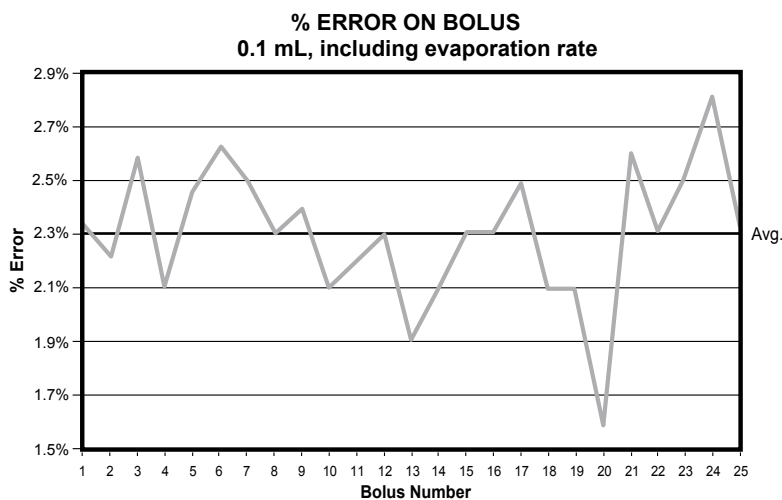
The following representative trumpet curves show flow rate deviation from the programmed rate over time. The curves give the percent error under different conditions of flow rate, delivery head pressures and for different periods of time. These graphs are applicable for all MARAA PCA Infusion Pump Cassettes.

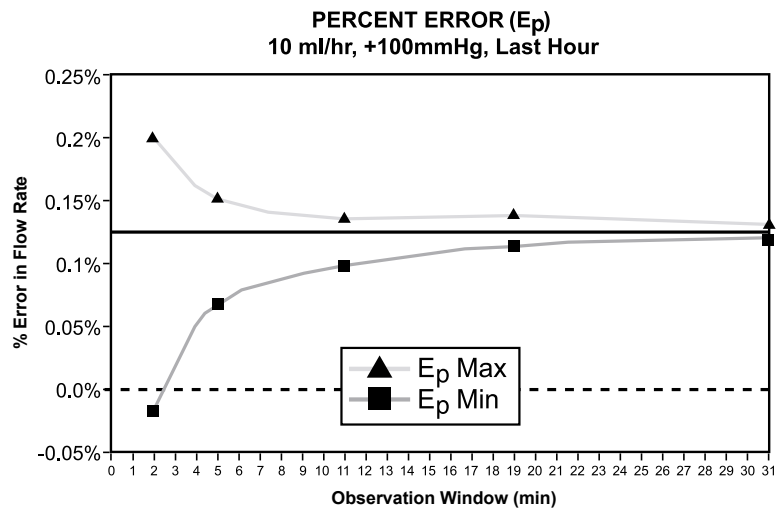
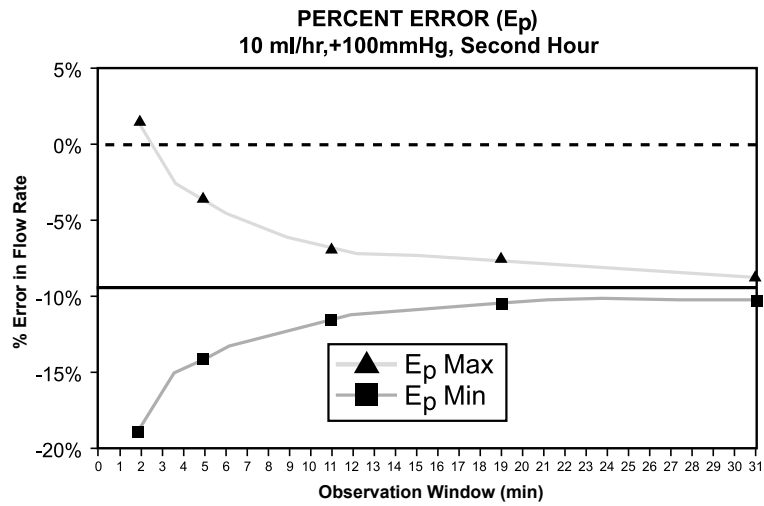
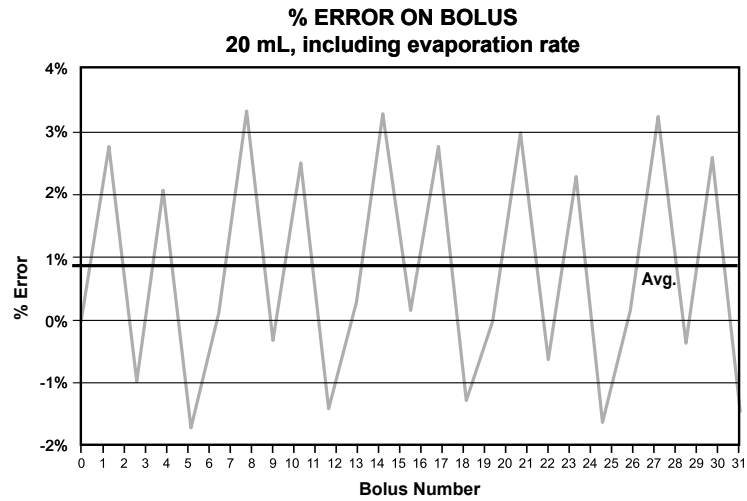
When the time interval over which the accuracy is measured is shortened, all pumps show considerable variations of flow pattern. For instance, all pumps that have pulsed flow (such as peristaltic, diaphragm, and piston pumps) show an increase in volumetric accuracy as the observation window is expanded. The graphs that follow show this increase in volumetric accuracy.

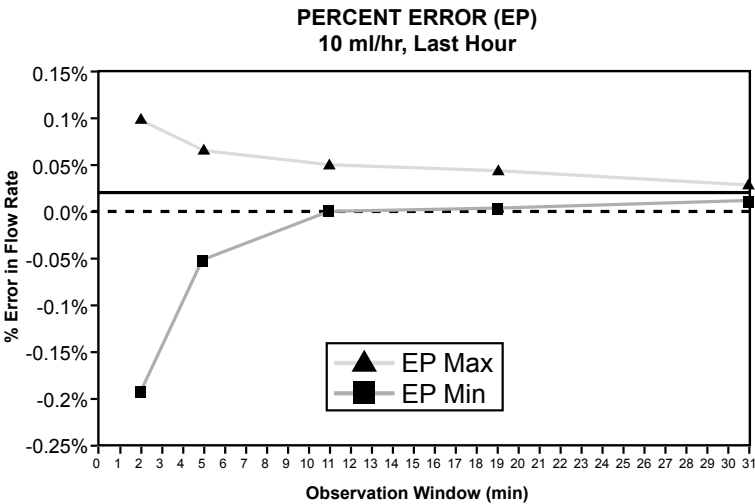
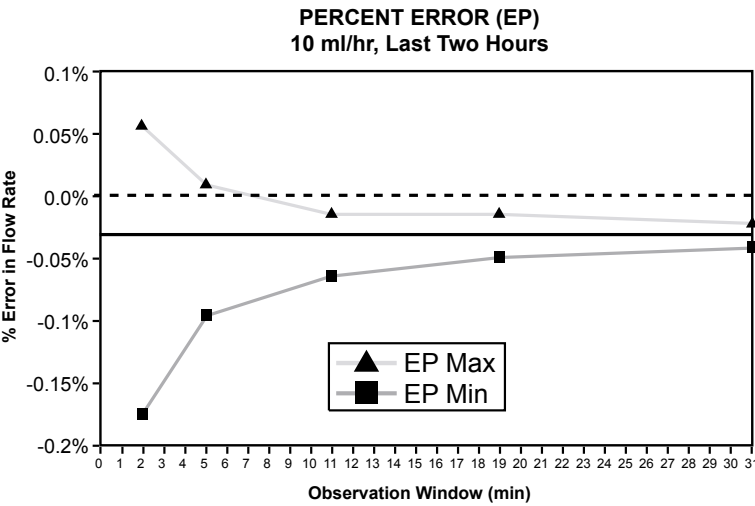
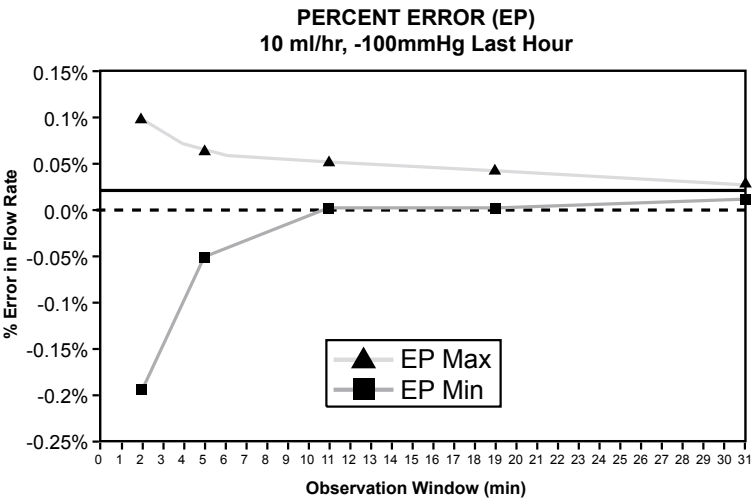
The MARAA PCA Infusion Pump uses a rotary peristaltic mechanism to deliver fluid. The Pump completes a stroke in about a second, then is idle until the next stroke is due. Thus the instantaneous rate error may exceed 6%.

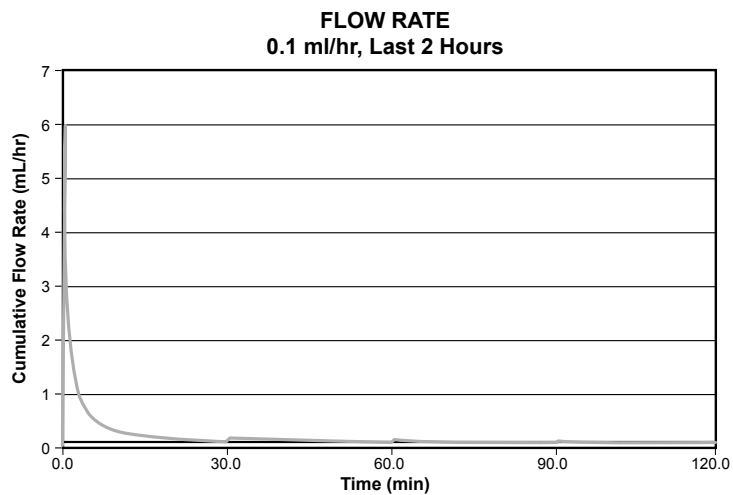
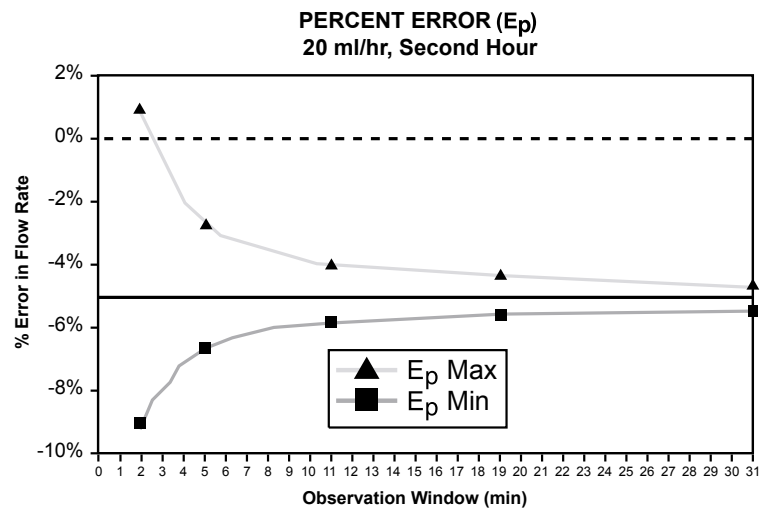
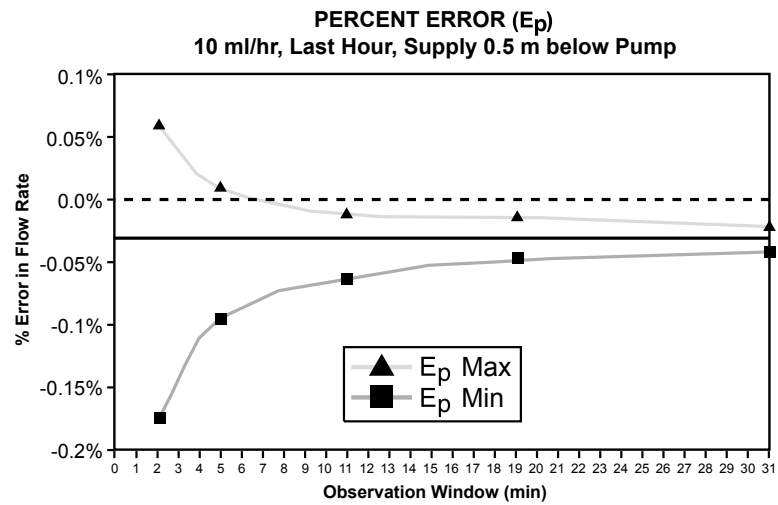
The user is directed to be aware of the delivery profile of the Pump as shown in the graphs below and on the next three (3) pages to ensure that it is acceptable for the drug being infused, its concentration and rate of delivery.

Pulling fluid from a syringe will affect volumetric accuracy.









SECTION 11

GENERAL CARE INSTRUCTIONS

The patient should be careful to protect the Pump at all times. The Pump should not be dropped, stored in freezing -7°C (20°F) temperatures, left in direct sunlight or exposed to excessive heat 70°C (158°F). The Pump should only be operated between 10°C and 43°C (50°F and 110°F).

Pump and components should be stored in a dry, cool place until used.

The Pump can be cleaned by wiping its surface with a slightly damp cloth. Use only mild detergent soaps.

To disinfect the Pump, use a cloth slightly dampened with any of the following:

- A fresh solution of one (1) part household bleach to nine (9) parts water.
- 70% Isopropyl alcohol.
- Equivalent disinfectant product.

Warning:

Pump failure may be caused by the application of cleaning solutions other than those recommended by the manufacturer.

Do not immerse the Pump or sterile Cassette in any cleaning solutions.

Note:

For storage and transporting the Pump, a cap should be placed on the Pump to protect the pressure switch.

11.1 Warranty Information

The MARAA PCA Infusion Pump is covered by a Manufacturer's warranty to be free from defects in materials and workmanship for six (6) months from date of purchase. During this time, opening the pump for any reason except for changing the batteries voids this warranty. The MARAA PCA Infusion Pump contains no serviceable parts.

This warranty will not apply to ambIT® Pumps that have been in Sorenson Medical's judgement damaged whole or in part due to misuse, abuse, negligence, alteration, improper installation, dropped or otherwise used in a manner inconsistent with its labeling and packaging.

To obtain warranty service, the pump and cassette must be returned to Sorenson Medical, Inc. postage prepaid. The replacement of a pump and cassette will not extend the original term set forth above.

SECTION 12

CUSTOMER ASSISTANCE

For Customer Assistance, please contact your distributor or Sorenson Medical, Inc. at:

Sorenson Medical, Inc.
1375 West 8040 South
West Jordan, Utah 84088-8320, USA

Toll Free: (877) 352-1888

Phone: (801) 352-1888

Fax: (801) 352-1818

e-mail: service@sorensonmedical.com

Web Site: www.sorensonmedical.com

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FINDING BETTER WAYS TO CARE FOR PEOPLE™